Ecological Risk Assessment

Utility of RA for Biosolids

"In section 405 of the CWA, Congress, for the first time, set forth a comprehensive program designed to reduce potential health and environmental <u>risks</u> and maximize the beneficial use of sewage sludge." (Fed Reg 12/31/2003, page 75531)

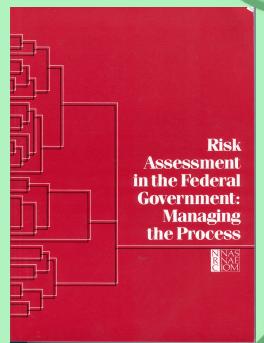
405(d)(2)(A) – "... regulation should be based on 'available information on toxicity, persistence, concentration, mobility, and potential for exposure."

EPA 503 intended to comply with 405(d)

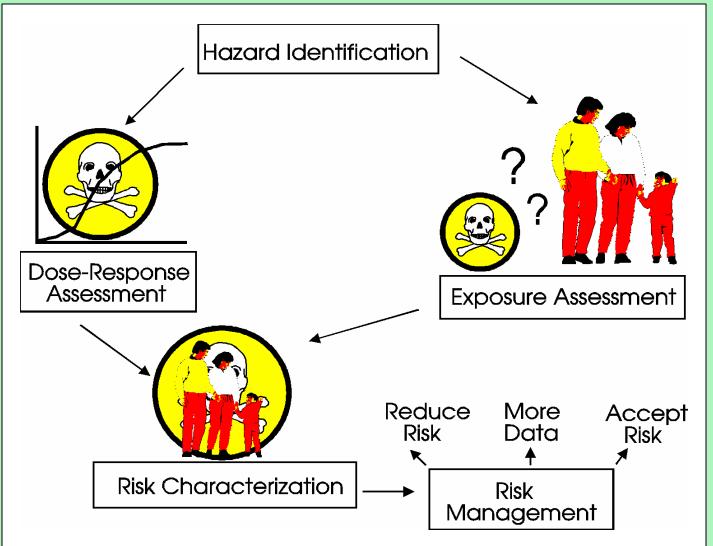
The intent of 405 and specific approach to biosolids regulation was addressed by the NAS with a risk assessment (RA) framework.

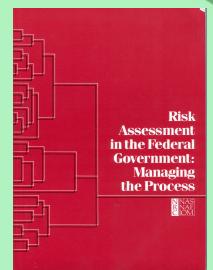
Risk Assessment Paradigm

The NAS (National Research Council (1983) developed the paradigm used in risk assessments today. This report, Risk Assessment in the Federal Government: Managing the Process was focused on human risk assessment and gradually became known as "the NAS Red Book."



Risk Assessment Paradigm





GOAL

Ecological RA aims to estimate the likelihood of a specified adverse effect or ecological event due to a defined exposure to a stressor (or set of stressors).

Relevant effects can range from suborganismal to global scale.

- cancer in a species at an Elizabeth River Superfund site
- landfill leachate impact on a wetland plant community
- risk from a VA biosolids disposal decision
- coal burning and global mercury dispersal/exposure



Unlike human RA, ERA considers many diverse species.

It might even consider ecological entities, e.g., communities, composed of many interdependent species occupying a heterogeneous landscape.

Also, in contrast to human RA in which extrapolation to one species (humans) is often done from many species (e.g., mouse, rat, or dog toxicity data), ERA extrapolates from one or a few species to many.





TYPES OF ERA

Ecological assessments may be retroactive or predictive.

- Predictive assessments adhere to the NAS paradigm Application and Cd bioavailability with soil type/pH
- Retroactive assessments relay more on surveys of contamination and ecological impact, models of fate and effects, and epidemiological data

Ecological RA can (less frequently) be comparative RA

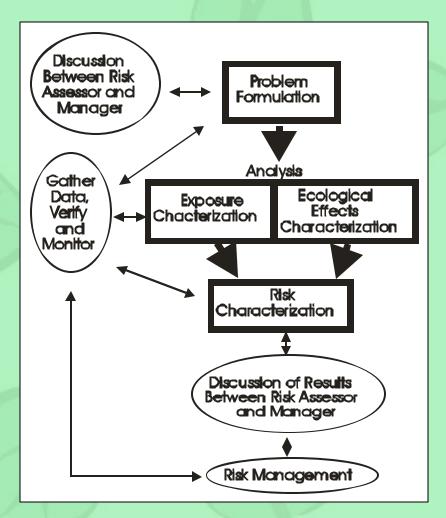
- Land application vs incineration vs landfill for disposal
- Land application without vs with various types of buffer zones
- Land application with or without composting or alkali adjustment
- Likely will become more common as regulation moves toward more life-cycle assessments

The ecological risk assessment process is organized like the NAS paradigm, with the same overall logic.

- Problem formulation
 Involving risk assessor & manager
- Analysis step Has two parts
 1a. exposure characterization
 2a. ecological effects characterization
 It also has parts of the hazard
 identification component of the
 NAS paradigm.

In stages 1 & 2, there might be re-examination of various actions or decisions as new information arises.

3. **Risk characterization**Bring everything together.



Problem formulation

Includes the initial planning and scoping that establishes the framework for the risk assessment.

Includes the selection of assessment endpoints, a conceptual model, and a plan of analysis. Very difficult and critical step.

Assessment endpoint - the valued ecological entity to be protected (e.g., bald eagles nesting by a contaminated lake) and the precise quality to be measured for this entity (e.g., nesting success of bald eagles).

Sometimes the distinction is made that

- assessment endpoint or receptor is the entity to be protected
- measurement endpoint is the measured response that is related to the valued assessment endpoint.
 - Some logical or quantitative model must link the two endpoints.

Qualities of an Ecological Receptor to Be Considered

- 1. Favor receptors that are ecologically relevant to the ecosystem under study.
- 2. Select a receptor that is susceptible to the contaminant.
- 3. Favor receptors that are valued by society.
- 4. Favor receptors with unambiguous operational definitions.
- 5. Favor those most readily measured directly or most easily predicted from other measurements



Conceptual model

Links the assessment endpoint and the stressor(s).

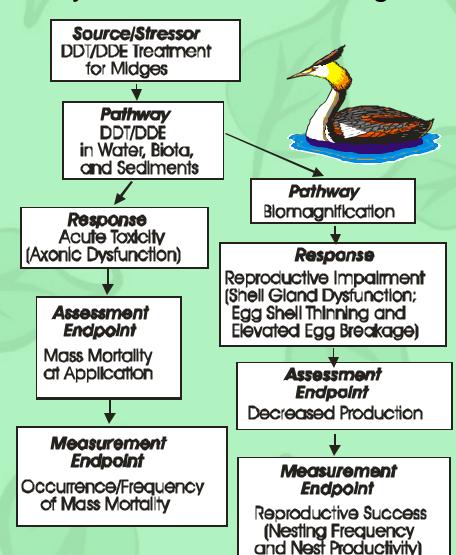
Evaluates possible exposure pathways, effects, and ecological

receptors.

Conceptual models include hypotheses of risk and a diagram of the conceptual model.

Risk hypotheses are clear statements of postulated or predicted effects of the stressor on the assessment endpoint.

The conceptual model diagram shows the pathways of exposure and illustrates areas of uncertainty or concern. It is a visual aid for communicating to the risk manager.



Risk Hypotheses & Analysis Plan

Risk hypotheses are examined carefully and a plan of analysis is produced.

An analysis plan defines the format and design of the assessment, explicitly states the required data, and describes the methods and design for data analysis.

It describes what will or will not be analyzed.

Only metals, metals & helminth ova, or metals, ah receptor organics & ova?

Measurement endpoints are stated in the analysis plan.

A measurement endpoint may involve measurements derived directly from the valued ecological entity or from its surrogate.

Analysis

Analysis step has two components

- exposure characterization
- ecological effects characterization



Together they are very similar to the exposure and doseresponse assessments of the NAS paradigm.

The exposure and ecological effects characterizations are done in tandem with exchange of information occurring between the two components.



Exposure characterization

Describes characteristics of contact between the contaminant & the ecological entity.

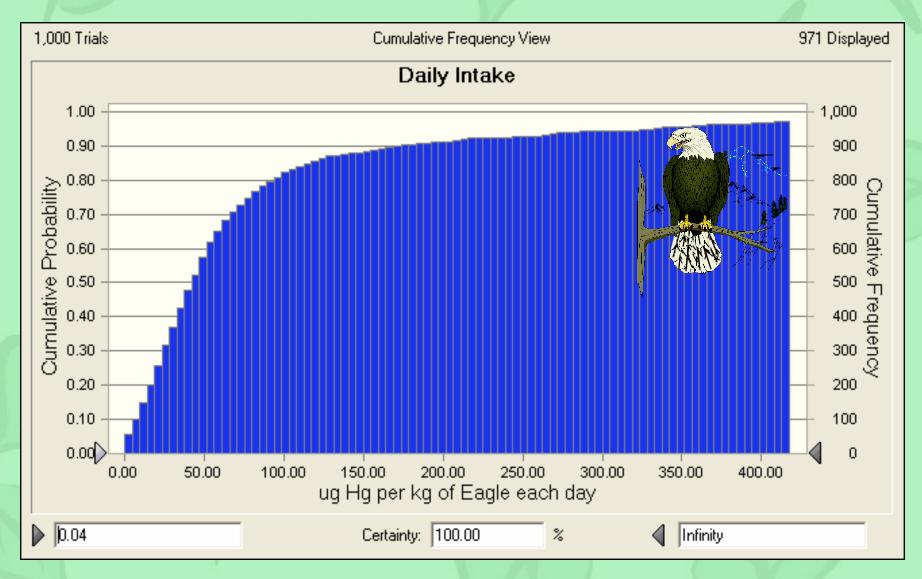
Temporal and spatial patterns in contaminant distribution are defined in addition to the amount of contaminant present.

The source of the contaminant, any potential co-stressors, transport pathways, and type of contact are defined.

Quantitative methods used for human exposure assessment are applied. Concentration, duration, and frequency of exposure must be considered, including consideration of factors such as seasonal cycles and home ranges of species.

The final exposure profile "quantifies the magnitude, and spatial and temporal pattern of exposure for the scenarios developed during problem formulation" Can be probabilistic.

Probabilistic Mercury Exposure Characterization Bald eagle of Great Dismal Swamp Refuge



Ecological effects characterization

"Describes the effects that are elicited by a stressor, links these effects with the assessment endpoints, and evaluates how effects change with varying stressor levels."

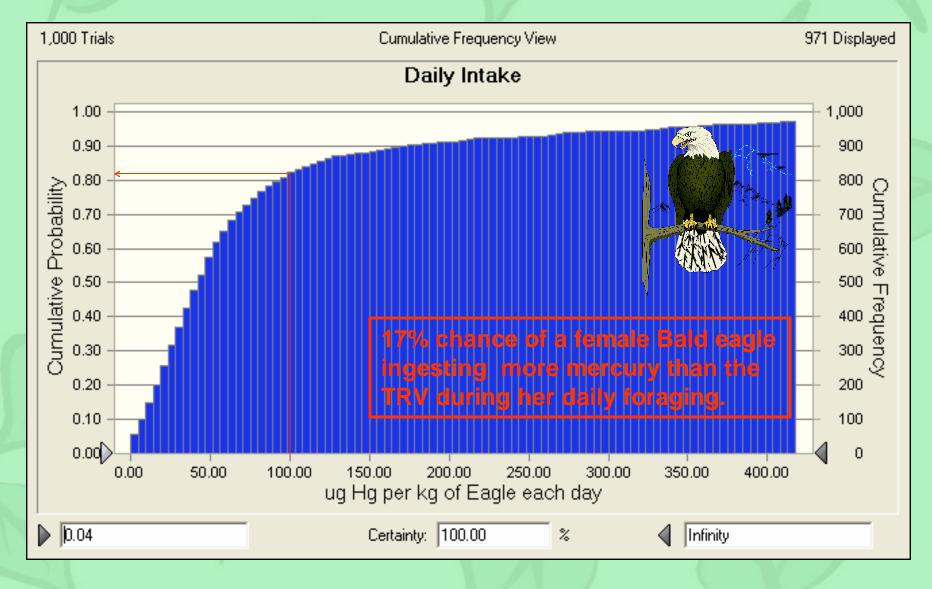
Also specifies the strength of evidence associated with the effects characterization, and level of confidence in the causal linkage between the contaminant and the effect.

Information generated with many of the methods described previously are brought together to develop a stressor-response profile for the valued ecological entity. Can use databases such as ECOTOX,

http://www.epa.gov/ecotox/

Unfortunately, the imbalance between available information and that needed compromises ecological risk assessments. Most information is for effects to individuals.

Probabilistic Mercury Exposure Characterization Bald eagle of Great Dismal Swamp Refuge

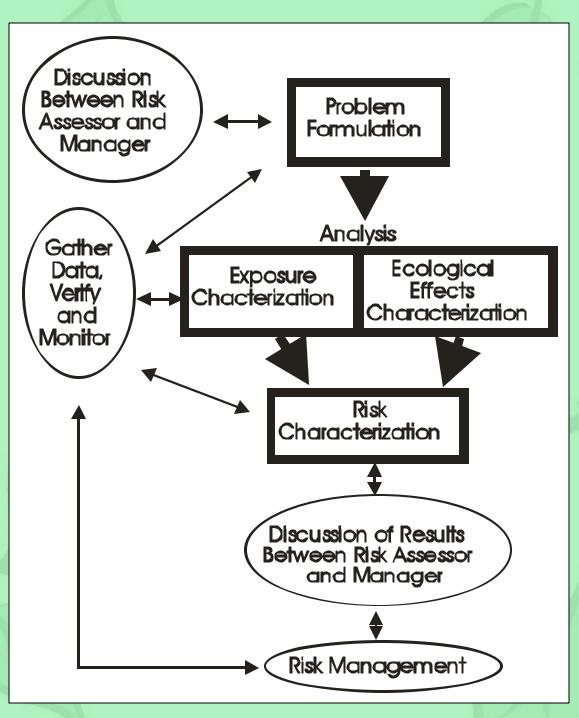


Risk characterization

Draws together all information to produce a statement of the likelihood of an adverse effect.

Risk may be expressed in several ways including a simple qualitative judgment or hazard quotient. It could involve description of the influences of concentration and temporal variations on estimates of effect. It could employ complex models that also generate some estimate of confidence in the risk predictions.

The final statement of risk must include details about the adequacy of the data going into the judgment, uncertainty involved in the conceptual mode or calculations, and weight of evidence for each causal relationship.



Questions?

"If seven maids with seven mops Swept it for half a year, Do you suppose," the Walrus said, That they could get it clear?" "I doubt it," said the Carpenter, And shed a bitter tear.

Lewis Carroll (1872)